K120557

MAR 19 2012

BIOMET SPINE

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

| | |
|---|---|
| **Preparation Date:** | February 23, 2012 |
| **Applicant/Sponsor:** | Biomet Spine and Bone Healing Technologies<br>100 Interpace Parkway<br>Parsippany, NJ 07054 |
| **Contact Person:** | Margaret F. Crowe<br>Phone: 973-299-9300, ext. 2260<br>Fax: 973-257-0232 |
| **Trade name:** | Solitaire PEEK Anterior Spinal System Line Extension (Solitaire 35°) |
| **Common Name:** | Lumbar stand-alone intervertebral body fusion device |
| **Classification Name (Product Code):** | Intervertebral Body Fusion Device with Integrated Fixation/Lumbar (OVD) |
| **Device Panel - Regulation No.:** | Orthopedic - 21 CFR 888.3080 |

**Device Description:**

This submission is for a line extension to the Solitaire PEEK Anterior Spinal System to add an additional style of spacer with a modified screw angle. This modified device will be marketed as Solitaire-35.

**Indications for Use:**

The Solitaire PEEK Anterior Spinal System is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

There is no change to the Indications for Use as a result of this design modification.

**Summary of Technologies:**

The technological characteristics of the new components are the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Solitaire PEEK-Optima Anterior Spinal System (Biomet Spine - K081395)
- Independence Spacer (Globus Medical - K082252)
- Expandable PEEK Spacer (Biomet Spine – K082406)

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**Performance Data:**
Mechanical testing was conducted in accordance with the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device". The testing conducted, along with the ASTM standard, are listed below:

- Static Axial Compression (ASTM F-2077)
- Dynamic Axial Compression (ASTM F-2077)
- Static Compression-Shear (ASTM F-2077)
- Dynamic Compression-Shear (ASTM F-2077)

An engineering analysis regarding implant subsidence was presented.

Mechanical testing shows the strength of the subject device is sufficient for its intended use.

**Substantial Equivalence:**
The modified spacers of the Solitaire PEEK Anterior Spinal System are substantially equivalent to the predicate spacers with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicate devices listed above are distributed for similar indications, and have similar design features.

**Conclusion:**
The subject device is substantially equivalent to its predicates when used as an intervertebral body fixation device. The indications for use and fundamental technology of the device remain unchanged. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject device to the other components in the Solitaire PEEK Anterior Spinal System. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 19 2012

Biomet Spine and Bone Healing Technologies
% Ms. Margaret F. Crowe
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K120557
Trade/Device Name: Solitaire® PEEK Anterior Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: February 23, 2012
Received: February 24, 2012

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

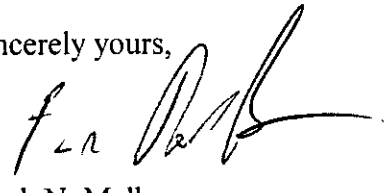
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4-1

Indications for Use Statement

510(k) Number (if known): K120557

Device Name: Solitaire® PEEK Anterior Spinal System

Indications for Use:
The Solitaire® PEEK Anterior Spinal System is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

| Prescription Use **X** (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120557